

1 Student's t test. Dichotomous data are subjected to
2 CHi square of Fisher's exact test, as is appropriate.

3 A power analysis was done to determine the number
4 of patients in each test group in order to show
5 predicted differences. Power analysis applied to an
6 ANOVA using a power of 0.80 with $\alpha = 0.05$, coupled with
7 prior studies of mean ALT levels and their variances,
8 estimated a need for 21 to 52 patients in each test
9 group to show a mean ALT difference of 15 IU/L. As 3
10 to 5% of patients are expected to drop out, and
11 factoring in treatment of the control group after six
12 months, 40 patients per group was arrived at.

13 We Claim:

14 1. A method of treating a mammal infected with
15 hepatitis C virus, comprising administering to said
16 mammal an anti-viral effective amount of at least one
17 interferon, concurrently or sequentially with
18 administering said thymosin or thymosin fragment.

19 2. A method of Claim 1, wherein said interferon
20 is selected from the group consisting of α -, β - and γ -
21 interferons.

22 3. A method of Claim 2, wherein said α -interferon
23 is interferon α -2b.

24 4. A method of Claim 1, wherein the step of
25 administering said interferon comprises administering
26 interferon produced by recombinant DNA technology.

10. A composition of Claim 9, wherein said α -
interferon is interferon α -2b.

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11. A composition of Claim 10, wherein said
interferon is recombinant interferon.

12. The composition of Claim 7, wherein said
thymosin is Thymosin Fraction Five, the immune system-
potentiating amount is a human immune system-
potentiating amount, and said pharmaceutical dosage
unit is from about 900 to about 1200 mg/m² body surface
area of said human.

13. The composition of Claim 7, wherein said
interferon is an α interferon and said amount is between
about 1 million and about 3 million units of said
interferon.

14. The composition of Claim 7, wherein said
thymosin is Thymosin α -1, said immune system-
potentiating amount is a human immune system-
potentiating amount, and said pharmaceutical dosage
unit is from about 900 to about 1200 μ g/m² body surface
area of said human.

15. The composition of Claim 7, wherein said
thymosin is Thymosin α -1, and said pharmaceutical
dosage unit contains about 1500 to about 1700 μ g of
Thymosin α -1.

16. An anti-hepatitis C formulation comprising an
immune sytem-potentiating amount of at least one
thymosin or an immune system-potentiating thymosin
fragment in combination with an anti-viral effective

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A/C

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A7

Sub B3

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As
1 amount of at least one interferon in a pharmaceutically
2 acceptable carrier, for use in the treatment of a
3 mammal infected with hepatitis C virus.

4 17. The formulation of claim 16, wherein said
5 thymosin is selected from the group consisting of
6 Thymosin Fraction Five and Thymosin α -1.

7 18. The formulation of Claim 16, wherein said
8 interferon is selected from the group consisting of α -,
9 β -, and γ -interferons.

10 19. The formulation of Claim 18, wherein said α -
11 interferon is interferon α -2B.

12 20. The formulation of Claim 19, wherein said
13 interferon is recombinant interferon.

14 21. The formulation of Claim 16, wherein said
15 thymosin is Thymosin Fraction Five, said immune system-
16 potentiating amount is a human immune system-
17 potentiating amount, and said amount is from about 900
18 to about 1200 mg/m² body surface area of said human.

19 22. The formulation of Claim 16, wherein said
20 interferon is α -interferon and wherein said anti-viral
21 effective amount is from about 1 million to about 3
22 million units of said interferon.

23 23. The formulation of Claim 16, wherein said
24 thymosin is Thymosin α -1, said immune system-
25 potentiating amount is a human immune system-

24. The formulation of Claim 16, wherein said thymosin is Thymosin α -1, and wherein said amount is about 1500 to about 1700 μ g of Thymosin α -1.